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10/665,937	09/18/2003	Gunther Bellmann	P02428-C1	6818

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Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER	
FAY, ZOHREH A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/665,937
Filing Date: September 18, 2003
Appellant(s): BELLMANN ET AL.

John Thomas
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 25, 2006 appealing from the Office action mailed February 1, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,861,760	Mazuel et al.	8-1989
5,304,559	Rozier	4-1994

GB 2007091 Kamishita et al. 5-1979

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazuel et al. (U.S. Patent 4,861,760) in view of Rozier (U.S. Patent 5,304,559) and GB Patent Application 2007091.

Mazuel et al. teach the use of dexamethasone sodium phosphate in combination with mannitol, EDTA and benzalkonium chloride, which is intended to gel upon administration. See column 5, lines 59-63, column 6, lines 49 and 50 and example 3. The above reference differs from the claimed invention in the claimed specific PH, specific preservative of claim 14 and having the gel form prior to the administration to the eye. Rozier teaches that the claimed PH range for ophthalmic composition as old. See column 2, lines 57-65. Rozier also teaches the use of benzododecinium salt as a preservative in ophthalmic formulations as old. GB Patent teaches an ophthalmic composition in a gel form at the PH of 5-8. See the abstract. The above reference also teaches the use of different dexamethasone salts in such gel formulation. See page 1, lines115-130. It would have been obvious for a person skilled in the art to use dexamethasone in a gel form at the claim PH, considering that Rozie and GB Patent teach the claimed PH for ophthalmic formulation and especially for compositions having dexamethasone as old and well known. Rozier also teach that benzododecinum salt as a preservative in ophthalmic formulations as old. GB Patent Application also teaches the use of dexamethasone as gel in ophthalmic formulations as old.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of dexamethasone sodium phosphate in combination with mannitol, EDTA and benzalkonium chloride in an ophthalmic

formulation, Rozier relates to the use of benzododecinium salt and the claimed PH in ophthalmic formulations as old and GB Patent teaches the use of dexamethasone in a gel form at the claimed PH. The above references in combination make clear that the use of dexamethasone in a gel form at the claimed PH as old and well known. The above references in combination also make clear that the use of the claimed preservatives and secondary components in ophthalmic formulations as old. Appellant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 7-16 are properly rejected under 35 U.S.C. 103 (a).

(10) Response to Argument

Appellant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Appellant in his remarks argues that none the references recognizes any problem with stability of dexamethasone dihydrogen phosphate gel preparations and suggesting adjusting PH to the claimed pH range in order to obtain a more stable composition. The arguments are not well taken. The GB Patent teaches a gel formulation at the claimed PH, which can contain dexamethasone derivatives. The other relied upon references teach the use of secondary components in such composition as old. Appellant also alleges criticality to the more stable composition of the claimed invention at the claimed PH. The allegation is not well taken. The presented data to support the claimed stability are not convincing, considering that such

data are not commensurate with the claimed language. Furthermore, PH is not the only variable in the comparative example.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

Zohreh Fay

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Conferees:

Michael Hartley

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

Jean Witz

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER